

5876. Super Rybutol gelucaps. (F.D.C. No. 42560. S. No. 24-426 P.)

QUANTITY: 220 60-capsule btl. at Los Angeles, Calif.

SHIPPED: Between 2-3-58 and 6-13-58, from St. Louis, Mo.

RESULTS OF INVESTIGATION: Examination showed that the article contained approximately 80 percent of the declared amount of vitamin B₁.

LIBELED: 12-31-58, S. Dist. Calif.

CHARGE: 501(c)—while held for sale, the strength of the article differed from that which it purported and was represented to possess, namely, 15 milligrams of vitamin B₁ per capsule; and 502(a)—the labeling of the article contained false and misleading representations that it was an effective treatment for loss of energy, lack of appetite, nervousness, and indigestion.

The libel alleged also that certain other quantities of Rybutol capsules were adulterated and misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 1-26-58. Default—destruction.

5877. Dex-All capsules. (F.D.C. No. 42601. S. No. 24-515 P.)

QUANTITY: 11 1,000-capsule btl., 2 500-capsule btl., and 40 100-capsule btl., at North Hollywood, Calif.

SHIPPED: 9-22-58, from Rensselaer, N.Y., by Delmar Pharmacal Corp.

LABEL IN PART: (Bulk container) "Del-Bardex #1 Timed Disintegration Capsule Each Capsule contains Dextro Amphetamine Sulfate 10 Mg. Amobarbital 60 Mg. * * * in a Special Base That Provides for the Disintegration of the Contents Throughout a Period of About 6-10 Hours * * * 25,000 Capsules, * * * Delmar Pharmacal Co., * * * Rensselaer, New York."

The capsules were repackaged into bottles from bulk stock as labeled above.

RESULTS OF INVESTIGATION: Analysis showed that the article contained labeled amounts of dextro-amphetamine sulfate and amobarbital of which 75 percent of the dextro-amphetamine sulfate was released in two hours.

LIBELED: 1-12-59, S. Dist. Calif.

CHARGE: 501(c)—when shipped, the quality of the article differed from that which it was purported or represented to possess in that it failed to disintegrate at a uniform rate over a 6 to 10 hour period; and (502(a)—the label statement "in a Special Base That Provides for the Disintegration of the Contents throughout a Period of About 6-10 hours" was false and misleading.

DISPOSITION: 2-5-59. Default—destruction.

5878. Contact lens wetting solution. (F.D.C. No. 43178. S. Nos. 57-699/700 P.)

QUANTITY: 480 2-oz. btl. and 2,000 5-cc. btl. at New York, N.Y.

SHIPPED: 2-13-59, from Wauconda, Ill., by Mi-Con Laboratories.

LABEL IN PART: (Btl.) "UCL Wetting Solution An antiseptic, wetting and cleansing solution to be used with plastic contact lenses. Directions: * * * Active ingredients: Alkyl dimethyl benzyl ammonium chloride 1:25000 distributed by United Contact Lens Corp. 76 Madison Ave., New York 16, N.Y." or "5 cc. * * * UCL Wetting Solution Directions * * * distributed by United Contact Lens Corp. 76 Madison Ave., New York 16, N.Y."

RESULTS OF INVESTIGATION: Examination showed that the article was contaminated with large numbers of viable micro-organisms.

LIBELED: 7-14-59, S. Dist. N.Y.

CHARGE: 501(c)—when shipped, the purity and quality of the article fell below that which it purported and was represented to possess, since it purported to be suitable for use in the eye and for cleaning contact lenses and rendering them free from microbial contamination; whereas it was not suitable for such uses and purposes since it was contaminated with large numbers of viable micro-organisms.

DISPOSITION: 8-5-59. Default—destruction.

5879. Rectal thermometers. (F.D.C. No. 42539. S. No. 32-231 P.)

QUANTITY: 264 rectal thermometers in envelopes at Englewood, N.J.

SHIPPED: 10-7-58, from Brooklyn, N.Y., by Adelphi Surgical Co., Inc.

LABEL IN PART: (Envelope) "Certificate of Examination Fever Thermometer * * * issued by the United States Dept. of Commerce Comet Thermometer Co., Brooklyn, N.Y. [or Cardinal Thermometer Co., Brooklyn, N.Y.]" and (engraved on thermometer) "Adelco Rectal."

RESULTS OF INVESTIGATION: Examination of 24 thermometers showed that 13 failed to meet the requirement for accuracy specified in CS1-52, issued by the National Bureau of Standards, when tested as described in CS1-52.

LIBELED: 12-5-58, Dist. N.J.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it purported and was represented to possess since it did not give accurate readings; and 502(a)—the label statement "tested and found to meet all the requirements and tests specified in the Commercial Standard CS1-52" was false and misleading.

DISPOSITION: 1-12-59. Default—destruction.

5880. Rubber prophylactics. (F.D.C. No. 42695. S. No. 45-221 P.)

QUANTITY: 93 12-box ctns., each box containing 12 prophylactics, at Salt Lake City, Utah.

SHIPPED: 10-13-58, from North Kansas City, Mo., by Dean Rubber Mfg. Co.

LABEL IN PART: (Ctn.) "Peacocks The Original Reservoir Ends * * * Redi-Wet Rubbers in Foil * * * Dean Rubber Mfg. Co. North Kansas City, Mo.," (box) "Peacocks Redi-Wet Rubbers in Foil."

RESULTS OF INVESTIGATION: Examination of 288 prophylactics showed that 1.4 percent were defective since they contained holes.

LIBELED: 2-17-59, Dist. Utah.

CHARGE: 501(c)—the quality of the article, when shipped, fell below that which it purported to possess.

DISPOSITION: 4-24-59. Default—condemnation.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

5881. Arman's ear drops. (F.D.C. No. 42380. S. No. 27-319 P.)

QUANTITY: 40 btls. at Des Moines, Iowa.

SHIPPED: Between 8-29-58 and 10-14-58, from Omaha, Nebr., by Arman Drug Co., Inc.

*See also Nos. 5864, 5869-5872, 5875-5877, 5879.